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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,459	06/14/2001	Hiromi Ikadai	0020-4843P	7623
2292	7590	10/02/2003	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			BASKAR, PADMAVATHI	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747			1645	19
DATE MAILED: 10/02/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/807,459	IKADAI ET AL.
	Examiner	Art Unit
	Padmavathi v Baskar	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 7-10, 12 and 13 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4-6 and 11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. The amendment filed on 7/22/03 has been entered into the record. Claims 4-6 have been amended. Claims 1-3, 7-10 and 12-13 are withdrawn from consideration as non-elected invention, said election made in Paper No 14 (10/16/02) without traverse. Claims 4-6 and 11 are under examination.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

3. The Declaration under 37 CFR 1.132 filed on 7/25/03 (Paper # 18) is sufficient to overcome the rejection under 35 U.S.C. 102(a) as being anticipated by Kappmeyer et al 1999 (Journal of Clinical Microbiology, 37; 2285-2290) for claims 4 -6 and 11.
4. The Declaration filed on 7/25/03((Paper # 18) under 37 CFR 1.132 is sufficient to overcome the rejection under 35 U.S.C. 102(a) as being anticipated by as being anticipated by Ikadi et al1998, Accession No: ABO17700 or Abstract of 126 th conference on Japanese Society of Veterinary Science for claims 4 -6 and 11.
5. In view of the amendment to the claims, the rejection under 35 U.S.C. 112, second paragraph is withdrawn.

Rejections Maintained

6. The rejection of newly amended claims 4-6 and 11 under 35 U.S.C. 102(b) as being anticipated by Bose et al 1992 (International Journal of Parasitology, 22; 627-630) is maintained as set forth in the previous office action.

Claims are now directed to an isolated recombinant protein from merozoites of *B.caballi*, said recombinant protein has the amino acid sequence shown in SEQ.ID.NO: 2 or cDNA having

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the nucleotide sequence encoding the amino acid sequence shown in SEQ.ID.NO: 2 with one to several amino acid residues therein being deleted, substituted or added, is incorporated into the DNA vector. Claim is also drawn to an antigen comprising the recombinant protein, said protein is immunologically reactive with an antibody or antiserum elicited by a 48KD protein of rhoptry from *B.caballi* merozoite.

Bose et al disclose 48KD and 50KD proteins from *B.caballi* and are immunologically reactive with infected horse sera (see page 629, under Discussion, abstract and figure 1). In the absence of evidence to the contrary, these proteins contain the amino acid sequence as shown in SEQ.ID.NO: 2. Claims 4-6 and 11 are drawn to recombinant proteins based on product-by-process limitations. Although product-by-process claims are limited and defined by the process, nonetheless, determination of patentability is based on the product itself. The patentability of a product does not depend upon its method of production. If the product in the product-by-process claim is the same as or an obvious variant of the product of the prior art, the claim is unpatentable even though a different process made the product. Multiple routes can obtain the recitation of a process limitation in claims "recombinant" is not seen as further limiting the claimed product, as it is presumed the equivalent products. Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to provide evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). *In re Marosi*, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

Applicant states that claim 6 is free of this rejection. The examiner should note that the subject matter of claim 6 is incorporated into claim 4. Thus, the rejection is moot and should be withdrawn. The examiner further note that claim 4 has been amended to include the following limitation: " cDNA having the nucleotide sequence encoding the amino acid sequence shown in SEQ.ID.NO: 2 with one to several amino acid residues therein being deleted, substituted or added, is incorporated into the DNA vector".

The examiner has noted the amendment made to claim 4. However, the applicant did not argue about the rejection made under 35 U.S.C. 102(b) as being anticipated by Bose et al 1992 (International Journal of Parasitology, 22; 627-630).

The examiner has rejected the claims 4-6 and 11 that are drawn to a recombinant protein based on product-by-process limitation. As indicated, the claimed product can be obtained by multiple processes and Bose et al disclose such a 48KD protein from B.caballi and is immunologically reactive with infected horse sera (see page 629, under Discussion, abstract and figure 1). Therefore, in the absence of evidence to the contrary, the disclosed 48kD protein and the recombinant protein are the same. Applicants should provide evidence establishing an unobvious difference between the claimed product and the prior art product.

7. The rejection of claims 4-6 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated recombinant protein, said protein has the amino acid sequence shown in SEQ.ID.NO: 2 does not reasonably provide enablement for recombinant protein, where in said recombinant protein has the amino acid sequence shown in SEQ.ID.NO: 2 with one to several amino acid residues therein being deleted, substituted or added. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is maintained as set forth in the previous office action.

The specification is not enabled for a recombinant protein which has the amino acid sequence shown in SEQ.ID.NO: 2 with one to several amino acid residues therein being deleted, substituted or added because It is unclear to one skilled in the art what amino acids have been deleted or added or substituted in SEQ.ID.NO: 2. If it is unclear to one skilled in the art what amino acid sequences are embraced after these modifications which is based on a specification, the specification is non-enabling, since one skilled in the art would not be able to make and use those sequences without undue experimentation.

It is well known that for proteins, for example, even a single amino acid change can destroy the function of the biomolecule. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Further, specification is silent on how to make these proteins with sequence homology or variants or fragments. What changes would have an adverse effect on the function of this peptide is not predictable. It is known in the art that derivatives or variants, which are obtained by substitutions, deletions, or modifications of the amino acids of a protein, alter the function of the protein. The amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification),

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and detailed knowledge of the ways in which the proteins' structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex (Bowie et al. Science, Vol. 247: 1990; p. 1306; p. 1308) and is well outside the realm of routine experimentation.

Applicant states that the examiner indicated that the claims 4-6 are enabled "for an isolated recombinant protein" Accordingly, claims 4-6 are amended in the manner suggested by the examiner and therefore, the rejection should be withdrawn.

The examiner has clearly indicated that the claims are enable for " an isolated recombinant protein, said protein has the amino acid sequence shown in SEQ.ID.NO: 2". The examiner did not suggest any amendment to the claims in a manner as stated by the applicant. It is clear on the record that the claims are not enabled for a recombinant protein, wherein said recombinant protein has the amino acid sequence shown in SEQ.ID.NO: 2 with one to several amino acid residues therein being deleted, substituted or added. However, the claims as amended are not restricted to an isolated recombinant protein, said protein has the amino acid sequence shown in SEQ.ID.NO: 2". The newly amended claims broadly recite a recombinant protein SEQ.ID.NO: 2 with one to several amino acid residues therein being deleted, substituted or added as part of the invention. However, the specification fails to teach such recombinant proteins. Therefore, this rejection is maintained.

Status of Claims

8. Claims 4-6 and 11 are rejected.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

9/29/03

W
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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